

BASKET NO.: ORTU-0007

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Robert Raffa, et al.

Application No.: 10/761,096

Filing Date: January 20, 2004

For: COMPOSITIONS COMPRISING A TRAMADOL MATERIAL AND
ACETOMINOPHEN AND ITS USE

Confirmation No.: Not Yet Assigned

Group Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

DATE OF DEPOSIT: March 11, 2004

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Elizabeth A. McLoud

TYPED NAME: Elizabeth A. McLoud

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).



In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in § 1.491, before the mailing date

of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

☐ In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☐ Certification in Accordance with § 1.97(e) is attached;

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☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of \$180.00 as set forth in § 1.17(p).

☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

- ☒ Copies of references 4-121 and 143-151 listed on the attached Form PTO-1449 are enclosed herewith
- ☒ Copies of references 122-142 listed on the attached Form PTO 1449 are not required to be submitted pursuant to the June 30, 2003 revisions to 37 CFR § 1.98(a)(2)(i).

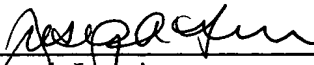
EXCEPT THAT:

- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☐ In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:
- ☐ Copies of references [list as appropriate] listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. _____, filed _____.

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- ☒ The relevance of those listed references which are not in the English language is as follows: Reference 48 was cited in the Australian Patent Office search report in related application AT 9605733-6, dated March 1999 (reference 109) as a document defining the general state of the art that was not considered to be of particular relevance.
- ☒ English language abstracts or translations have been provided for references 10-14, 18, 21, 22, 27, 31-34, 36, 37, 42-44, 47, 49, 52-55, 57-62, 65, 67-71, 75-77, 81-85, 87, 89, 91, 99-102, 105, 108, and 110 which are not in the English language.

Date: MARCH 11, 2004



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Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office		Docket No. ORTU-0007	Application No. 10/761,096
		Applicant Robert Raffa, et al.	
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	67	Mikić, B., et al., "Klinicko Ispitivanje Analgetika »Tramadol « u olbiku za oralnu upotrieu [Clinical investigation of the Analgetic "Tramadol" in the form for oral use]," <i>Acta orthop. Iugosl.</i> , 1985, 16(3), 93-96 (English translation – Exhibit A)	
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	72	Nickel B., "The antinociceptive activity of flupirtine: a structurally new analgesic," <i>Postgrad. Med. J.</i> , 1987, 63, 19-28	
	73	Padmasuta K., "Effects of Tramadol on postoperative wound pain in Thai patients," <i>Curr. Ther. Res.</i> , 1985, 38(2), 316-320	
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